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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,724	11/09/2000	Steven Istvan Ladunga	CL000841	2324

25748 7590 10/06/2003

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EXAMINER

PAK, MICHAEL D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 10/06/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/708,724

Applicant(s)

LADUNGA ET AL.

Examiner

Michael Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,8,9 and 24-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4, 8, 9, 24-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed 24 July 2003 (Paper No. 15) has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed 24 July 2003 (Paper No. 15), have been fully considered but they are not found persuasive.

Claim Rejections - 35 USC § 101

4. Claims 4, 8-9, and 24-29 remains rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicants cite *Nelson V. Bowler* as support for the notion that a recognized valuable addition to even entry points of the drug discovery cycle advances the art sufficient to establish a "usefulness" of a claimed invention. However, *Nelson V. Bowler* disclosed an assay where the prostaglandin compound worked whereas the claimed orphan receptor has no known function.

Applicants argue that the claimed SEQ ID NO:2 is similar to retinoic acid receptor responder secreted protein which has valuable commercial utilities in the drug discovery process by providing previously unidentified members of an important pharmaceutical

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target class. However, applicant provide not evidence of the retinoic acid receptor activity related to SEQ ID NO:2 which has utility. Examiner's sequence search disclosed no relationship between the claimed SEQ ID NO:2 and retinoic acid receptor activity in the state of the art. The closest prior art with closest amino acid sequence identity of 12% is another orphan protein with no known function.

Applicants argue that *Juicy Whip v. Orange Bang* provide support that in order to violate the utility requirement an invention must be "totally incapable of achieving a useful results." However, *Juicy Whip* invention is a beverage dispenser which may deceive and is not related to orphan protein. Applicants have not provided evidence that orphan receptors have utility without a known ligand which has utility.

Applicants argue that retinoic acid receptor responder secreted protein which has valuable commercial utilities in the drug discovery process by providing previously unidentified members of an important pharmaceutical target class. However, no evidence of relationship between retinoic acid and the orphan protein utility has been established.

The claims are drawn to a polynucleotide encoding a secreted protein which is an orphan polypeptide whose function is not known. The specification as filed does not disclose or provide evidence that points to a property of the claimed secreted protein such that another non-asserted utility would be well established. Since the function of the protein is not known, the protein lacks a well established utility. The specification on page 2 which disclose the asserted utility of using the secreted protein. However, there is no nexus between the unknown properties of the orphan secreted protein and any

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asserted utility. Thus, the general asserted utility lacks substantial utility because further research to identify or reasonably confirm a "real world" context of use is required. Any utility of the nucleic acid encoding the protein or other specific asserted utility is directly dependent on the function of the protein. A circular assertion of utility is created where the utility of the protein is needed to break out the circular assertion of utility. The polypeptides do not have substantial utility because the skilled artisan would need to prepare, isolate, and analyze the protein in order to determine its function and use. Therefore, the invention is not in readily available form. Instead, further experimentation of the protein itself would be required before it could be used. The disclosed use for the nucleic acid molecule of the claimed invention is generally applicable to any nucleic acid and therefore is not particular to the nucleic acid sequence claimed. The claims directed to vectors, host cells, and the process of expressing the protein do not have utility because the nucleic acid without utility is needed to practice the inventions. *Brenner V. Manson* 383 U.S. 519, 535-536, 148 USPQ 689, 696 (1966) stated that "Congress intended that no patents be granted on an chemical compound whose sole "utility" consists of its potential role as an object of use-testing ... a patent is not a hunting license." *Brenner* further states that "It is not a reward for the search, but compensation for its successful conclusion."

5. Claims 4, 8-9, and 24-29 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial

asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

6. No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Michael D. Pak

Michael Pak

Patent Examiner

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1 October 2003